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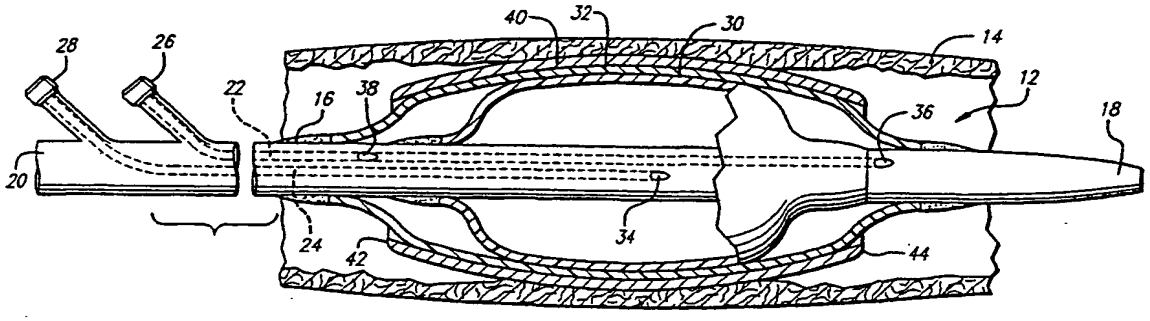
(54) Title: STENT DELIVERY DEVICE AND METHOD OF USE



(57) Abstract

A stent deployment system and method wherein a two-balloon catheter is used to expand the stent within a body lumen. The balloons are arranged concentrically about a dual lumen catheter wherein the inner balloon is smaller than the outer balloon. By first inflating the smaller balloon to expand only the center section of the stent, the stent undergoes substantially all of its longitudinal contraction before the ends make contact with the lumen tissue upon inflation of the larger outer balloon.

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STENT DELIVERY DEVICE AND METHOD OF USE

BACKGROUND OF THE INVENTION

The present invention generally relates to balloon catheters for implanting stents within a body lumen. More particularly, the invention pertains to improvements to such catheters in order to more effectively and reliably achieve a uniform expansion of such stents while minimizing trauma to the vessel wall.

Stents or expandable grafts are implanted in a variety of body lumens in order to prevent collapse and thereby maintain the patency of such lumens. In the case of angioplasty applications, stents may also be implanted to prevent restenosis and thereby similarly maintain patency in the affected blood vessel. The stent is introduced into the body in a collapsed state to facilitate its transport to the deployment site where it is subsequently expanded. One approach for achieving expansion requires the stent in its contracted state to be fitted about an inflatable balloon disposed near the distal end of a catheter. The entire assembly is advanced through the vasculature and maneuvered into the desired position adjacent the section of lumen in need of support. Once in position, the balloon is inflated, causing the stent to expand and engage the lumen walls. Various stent configurations and mechanisms have been devised to lock the stent into its expanded state in order to provide the requisite radial support to the lumen. Once the stent is fully expanded, the balloon is deflated and the catheter removed to leave the stent in place. Some stents are designed to permanently remain implanted while others are formed of materials that eventually become absorbed by the body.

The effectiveness of a stent can be diminished if it is not uniformly implanted within the body lumen. Stents expanded by the inflation of a balloon have a tendency to undergo a disproportionate rate and amount of radial expansion at their proximal and distal ends due to the typical drop off in hoop strength encountered near the ends of the structure. Thus the balloon expands along the path of least resistance in a "dog bone" pattern which is similarly imparted to the stent. Such

non-uniformity in the implanted stent may be problematic in that the desired flow diameter of the stent may not be achievable without forcing the stent ends deep into the lumen tissue. In the case of arterial applications, the non-uniformity of surfaces encountered by blood flow may cause turbulence, which in turn may lead to thrombosis.

A further disadvantage inherent in many stent configurations currently in use is that the structure undergoes longitudinal contraction as it is expanded radially. This characteristic, in conjunction with the tendency of the stent ends to expand first, has the potential for inflicting trauma on the lumen in which the stent is being deployed. Because the initial expansion of the stent ends may cause such ends to project into the lumen tissue, the subsequent radial expansion and hence longitudinal contraction of the center section would cause such ends to be pulled across the tissue. The rubbing or scraping of the stent against the tissue could cause injury.

This problem has been previously addressed in a number of ways including for example, the use of shape-defining sleeves that are fitted about the balloon. It is the intent of such systems to match the radial force profile generated by the balloon to the hoop strength of the stent and thereby to achieve a constant rate of expansion over the length of the stent.

Alternatively, multiple balloon systems have been employed in an effort to control the expansion of the stent. In one system, "control" balloons are positioned proximally and distally to a centrally disposed expansion balloon. The two control balloons check axial growth of the expansion balloon and hence prevent axially displaced lateral loads to be placed on the stent. As a further alternative, the stent is positioned over multiple balloons of varied compliance arranged in series along the catheter. By sequencing the inflation of the balloons such that the central balloon is inflated first, a more uniform implantation of the stent is achieved.

Nonetheless, those concerned with the design, development and use of stent implantation systems recognize the desirability of further improvements in terms of performance efficiency, reliability and reductions in the cost of manufacture.

SUMMARY OF THE INVENTION

The present invention overcomes the shortcomings inherent in heretofore known deployment devices and techniques for balloon expandable stents. More specifically, the present invention provides for the uniform deployment of such stents while obviating the trauma that the ends of the stent can inflict on the lumen walls. This is achieved more effectively and more reliably than was possible in the prior art and with a device that is less costly to manufacture than previously could be achieved.

The invention provides for the center section to be expanded before the ends of the stent are expanded, using a two-balloon system. As a result, the stent structure undergoes substantially its entire longitudinal contraction before the ends make contact with the vessel walls. The potential for the ends to be rubbed or scraped across the lumen tissue and to cause injury thereby is effectively obviated. This advantage is achieved with the use of two independently inflatable balloons which are fitted concentrically about a catheter. One balloon is positioned within the other balloon wherein the outer balloon corresponds to the length of the stent while the inner balloon is substantially shorter. The inflated diameter of the outer balloon is approximately equal to the inflated diameter of the inner balloon or is slightly smaller than the diameter of the outer balloon, in order to accommodate the diminished hoop strength of the ends of the stent.

The deployment device of the present invention allows the stent to be initially expanded by the inner balloon, which by virtue of its shorter length causes only the center section of the stent to be radially expanded. The stent undergoes the majority of its longitudinal contraction during such initial expansion and only after

such longitudinal contraction has been realized is the longer, outer balloon inflated to cause the ends of the stent to expand and match the diameter of the center section. Trauma to the vessel walls by the stent ends is effectively thereby avoided. The configuration of some stents and the commensurate hoop strength variations along the length of such stents may require the outer balloon to have a slightly smaller inflated diameter than the inner balloon, to avoid any "dog boning".

The use of only two balloons rather than the three balloons employed in some previously known in systems not only enhances reliability but also reduces manufacturing cost. The fact that the use of two balloons requires a lesser number of surfaces to be bonded and sealed to the catheter surface further enhances the reliability of the device. Moreover, in the event of the failure of the inner balloon, any expansion fluid that is lost is contained by the outer balloon. Moreover, the outer balloon can effect sufficient expansion of the stent to allow the catheter to be disengaged therefrom and withdrawn.

These and other features and advantages of the present invention will become apparent from the following detailed description of a preferred embodiment which, taken in conjunction with the accompanying drawings, illustrates by way of example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an enlarged, sectioned and cross-sectional view of an embodiment of the stent delivery system according to the present invention, prior to deployment of the stent;

FIG. 2 is an enlarged, sectioned and cross-sectional view of the stent delivery system of FIG. 1, after inflation of the inner balloon;

FIG. 3 is an enlarged, sectioned and cross-sectional view of the stent delivery system of FIG. 1, after inflation of the outer balloon; and

FIG. 4 is an enlarged, section and cross-sectional view of the stent delivery system of FIG. 1, with the inner balloon deflated so that the outer balloon can be fully inflated.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The figures generally illustrate an embodiment of a stent delivery system according to the present invention before, during and after deployment of the stent. Upon deployment, the stent serves to maintain the patency of the vessel in which it is positioned either by physically supporting the vessel wall or, in the case of some cardiovascular applications for example, by preventing restenosis.

FIG. 1 illustrates the system 12 in its pre-deployed, pre-implanted state upon having been advanced to the deployment site within a body lumen 14. The system is introduced into the body in the conventional manner and may be advanced into position via a guide wire using conventional over-the-wire or rapid-exchange catheter techniques. Details of representative stents can be found in U.S. Patent Nos. 5,421,955 (Lau et al.); 5,514,154 (Lau et al.); 5,603,721 (Lau et al.); and 5,569,295 (Lam), which are incorporated herein in the entirety by reference thereto. Details regarding balloon angioplasty catheters for use in performing angioplasty procedures, or that can be adapted to deliver intravascular stents are found in U.S. Patent Nos. 4,771,777 (Horzewski et al.); 5,501,227 (Yock); 5,350,395 (Yock); 5,451,233 (Yock); 5,300,085 (Yock); 5,496,346 (Horzewski et al.); 5,061,273 (Yock); 5,040,548 (Yock); 4,748,982 (Horzewski et al.); 5,626,600 (Horzewski et al.); and 4,323,071 (Simpson et al.), which are incorporated herein in the entirety by reference thereto.

The device includes a catheter 16 having a distal end 18 and a proximal end 20 wherein such catheter has at least two inflation lumens 22, 24 formed therein. Each inflation lumen is in fluid communication with an inflation port 26, 28 located near to the proximal end of the catheter.

Two inflatable balloons are fitted about the catheter near its distal end and are positioned such that the relatively shorter inner balloon 30 is wholly contained within the relatively larger outer balloon 32. The inner balloon is in fluid communication with lumen 24 via lumen port 34 while the outer balloon is in fluid communication with lumen 22 via lumen port 36 and optionally lumen port 38. The inflated diameters of the balloons are approximately equal or, optionally, the outer balloon may have a slightly smaller or larger inflated diameter than the inner balloon. The length of the inner balloon preferably is approximately 70% of that of the outer balloon, but preferably can be in the range of between 50% to 90% of the length of the outer balloon.

Fitted about the exterior surface of the outer balloon is the stent 40 that is to be deployed. The length of the outer balloon is selected so as to substantially conform to the length of the stent.

The balloons and catheter may be formed of polyethylene or other suitable materials well known in the art and the balloons preferably are bonded to the catheter as is also well known in the art.

In use, the catheter 16, with the balloons 30, 32 in the deflated state and supporting the stent 40 in the stent in its collapsed state thereabout, is introduced into the body lumen 14 and advanced therethrough to the deployment site. Once in position, the inner balloon 30 is inflated via the inflation port 28 to expand the center section of the stent 40 as is shown in FIG. 2. Such radial expansion causes the middle of the stent to expand radially outwardly and to simultaneously contract longitudinally. However, because the inner balloon does not engage the ends 42, 44 of the stent, the ends do not expand substantially and remain distanced from the lumen wall. Trauma to the lumen wall that would otherwise be inflicted by the ends

is avoided as the stent undergoes longitudinal contraction. Once the inner balloon is fully inflated, the outer balloon 32 is inflated via inflation port 26 as is shown in FIG. 3. In the event that two lumen ports 36, 38 are formed in the inflation lumen, there is no need to first deflate the inner balloon 30. In the event only a single lumen port is employed, it is necessary to first reduce the pressure within the inner balloon in order to provide a fluid pathway for the entire interior of the outer balloon into fluid communication with such single port, as shown in FIG. 4. As the outer balloon expands, the ends 42, 44 of the stent are expanded to their fully deployed state to impart a uniformly expanded profile to the stent. Deflation of both of the balloons 30, 32 leaves the stent 40 in place against the lumen walls and frees the catheter 16 for retraction.

The balloons preferably are inflated by radiopaque fluid to facilitate monitoring of the position and shape by fluoroscopic means. The details and mechanics of balloon inflation vary according to the specific design of the catheter and are well known in the art. Similarly, different stent configurations may require the relative sizes of the balloons and the pressures to which the balloons are inflated to be adjusted accordingly.

While a particular form of the invention has been illustrated and described, it will also be apparent to those skilled in the art that various modifications can be made without departing from the spirit and scope of the invention. The invention is not limited to the implantation of the stent in any particular body lumen nor to any particular configuration or size of the stent. Accordingly, it is not intended that the invention be limited except by the appended claims.

WHAT IS CLAIMED IS:

1. A deployment apparatus for an expandable stent, comprising:

a multi-lumen catheter dimensioned so as to be advanceable through vasculature to a deployment site;

an inner inflation balloon, having a first pre-selected inflated length and diameter, disposed about the catheter and in fluid communication with a first lumen that is formed in said catheter;

an outer inflation balloon, having a second pre-selected inflated length and diameter disposed about the catheter, wherein the inflated length of the outer balloon is greater than the inflated length of the inner balloon, wherein the inflated diameter of the outer balloon is no greater than the inflated diameter of the inner balloon and wherein the outer balloon is positioned to centrally contain the inner balloon.

2. The apparatus of claim 1, wherein the inner balloon is about 70% as long as the outer balloon.

3. The apparatus of claim 1, wherein the inner balloon is in the range of 50% to 90% as long as the outer balloon.

4. The apparatus of claim 1, wherein the inflated diameter of the outer balloon is less than the inflated diameter of the inner balloon.

5. The apparatus of claim 1, wherein the inflated length of the outer balloon is substantially equal to that of a stent to be deployed.

6. The apparatus of claim 1, wherein the inner balloon and the outer balloons are bonded to the catheter.

7. A method of deploying an expandable stent within a body lumen, comprising the steps of:

crimping a stent on to an outer inflation balloon containing a smaller centrally-located, inner inflation balloon, the balloons being disposed about a catheter;

advancing the stent and balloon-carrying catheter to a deployment site;

inflating the inner balloon to partially expand the stent; and

inflating the outer balloon to fully expand the stent.

8. The method of claim 7, further comprising the step of deflating the inner balloon prior to inflating the outer balloon.

9. The method of claim 7, wherein the inner balloon remains inflated as the outer balloon is inflated.

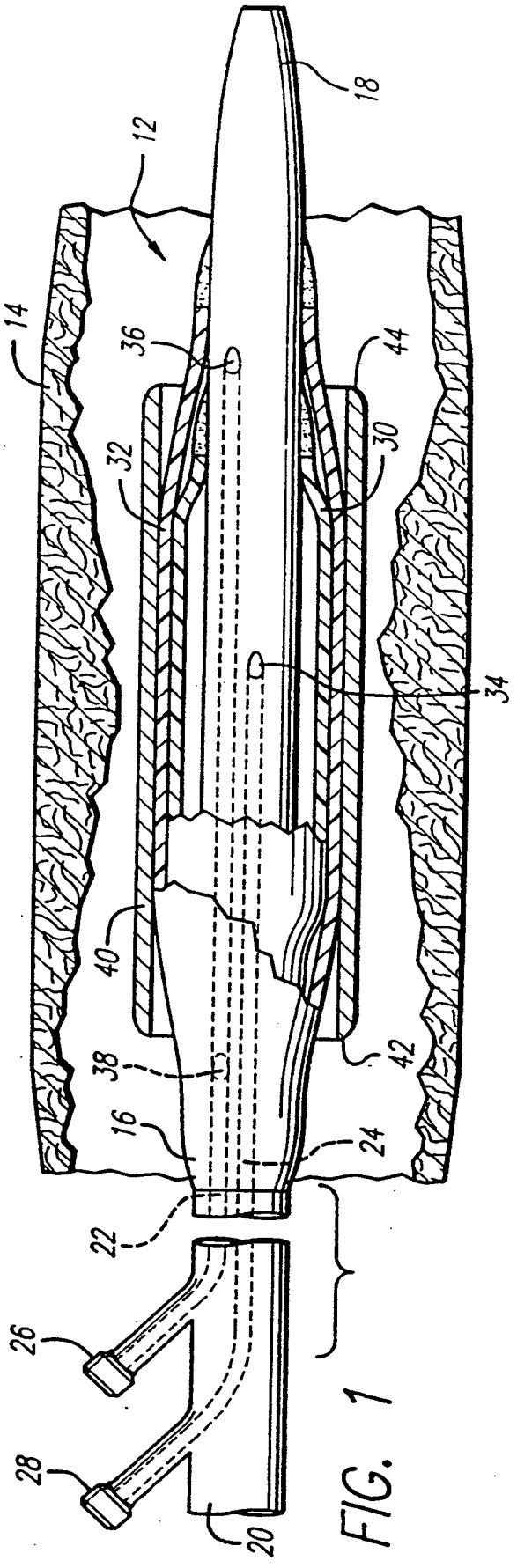


FIG. 1

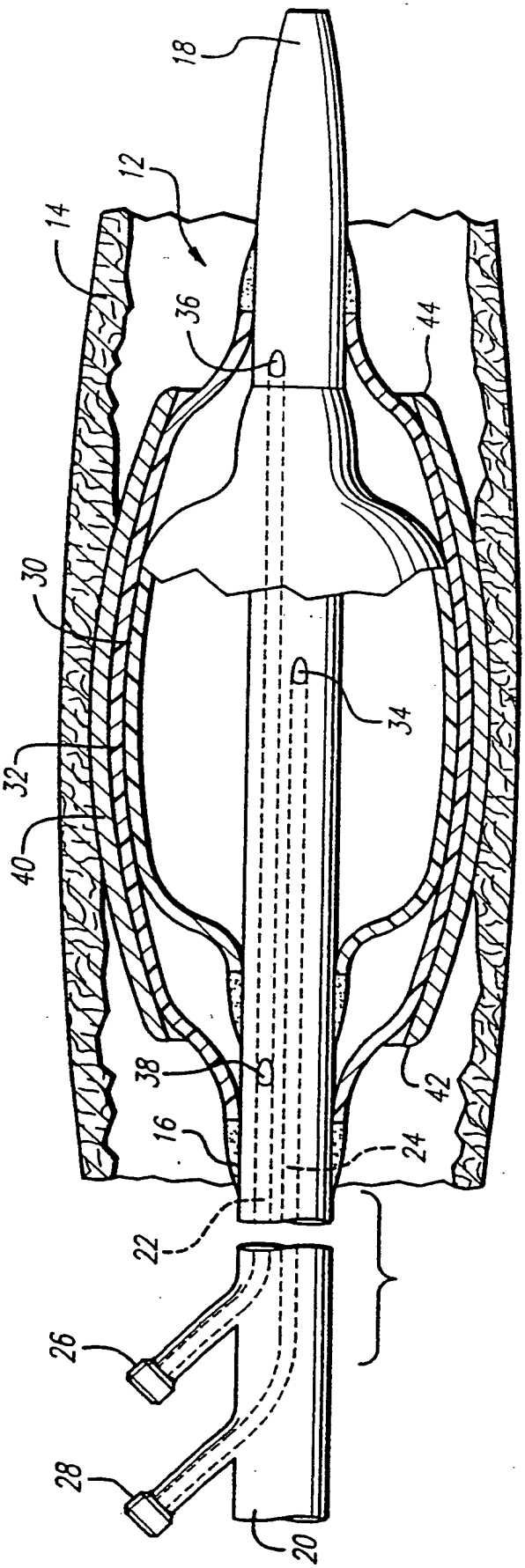
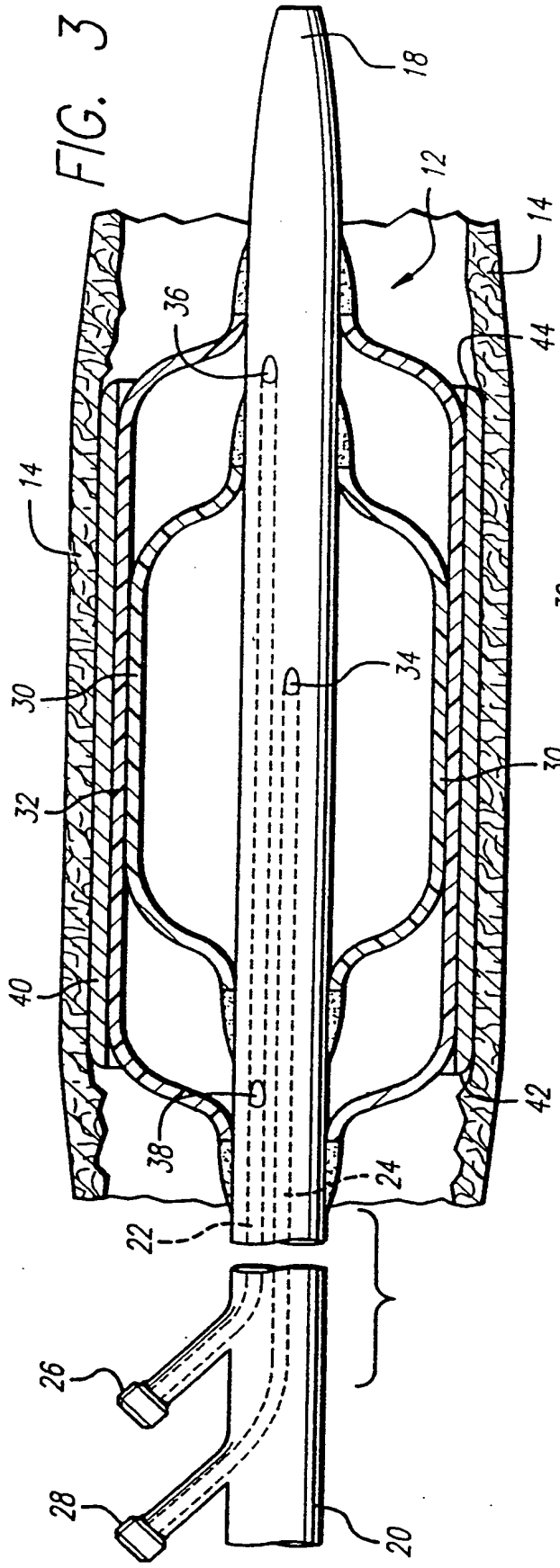


FIG. 2

FIG. 3



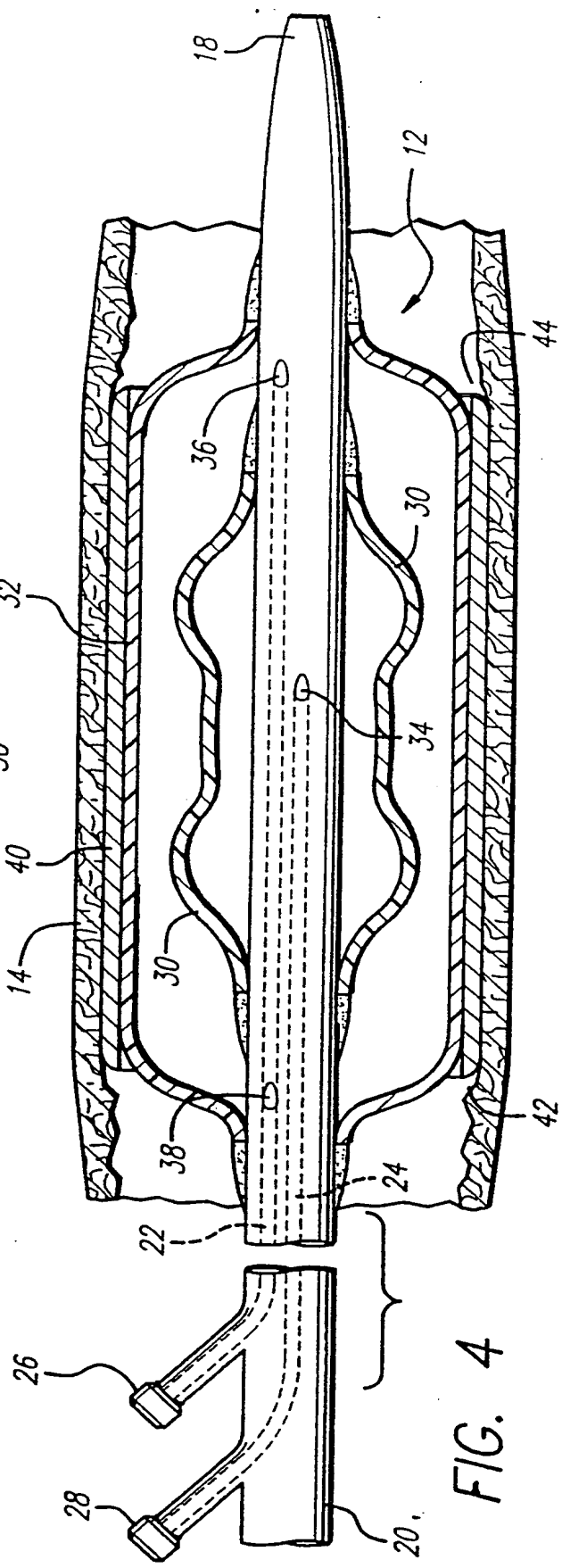


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/15792

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 725 535 A (BOURNE ET AL.) 10 March 1998 (1998-03-10) abstract; figures 1,2,4,6	1-6
X	US 5 653 689 A (BUELNA ET AL.) 5 August 1997 (1997-08-05) abstract; figures 12,13	1-6

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
11 October 1999	18/10/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Michels, N

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

.ernational application No.
PCT/US 99/15792

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 7-9
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 99/15792

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5725535 A	10-03-1998	AU 4416397 A	14-04-1998
		EP 0942766 A	22-09-1999
		WO 9811935 A	26-03-1998
		US 5788708 A	04-08-1998
US 5653689 A	05-08-1997	NONE	